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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,000	07/14/2003	Helene Depui	1103326-0250 CONT.	7466

7470 7590 05/17/2006

WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,000	DEPUI ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-14,22,25-28,33,34 and 37-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-14,22,25-28,33,34 and 37-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and remarks dated 3-8-06 is acknowledged.

Claims 1, 4-14, 22, 25-28, 33, 34 and 37-45 are pending.

Response to Arguments

Applicant's arguments with respect to claims 1, 4-14, 22, 25-28, 33, 34 and 37-45 have been considered but are moot in view of the new ground(s) of rejection.

The following is a new rejection:

Claim Rejections - 35 USC § 103

1. Claims 1, 4-14, 22, 25-28, 33, 34 and 37-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,786,505 to Lovgren et al (Lovgren) and EP 0426479 (EP) in view of US 6,136,344 to Depui et al (Depui) OR over US 6,136,344 to Depui et al Depui in view of EP 0426479 (EP).

Lovgren teaches a pharmaceutical preparation comprising proton pump inhibitor (PPI), omeprazole, optionally with an alkaline material as a core material and one or more sub coating layers comprising inert compounds and an enteric coating. Lovgren teaches the process of preparing the compositions. Lovgren teaches that the stability of omeprazole is maintained by protecting the compound from contact with gastric juices by adding an enteric coat over the compound, until it reaches small intestine without degradation (col. 1, lines 49-65). In order to increase the stability and rapid dissolution of omeprazole, Lovgren suggests preparing cores containing omeprazole mixed with an alkaline compound, which is further coated with two or more layers, one of which is

rapidly disintegrating in water and which separates the core from the enteric coating (col. 3, lines 14-33 and col. 4, lines 4-27). Lovgren also teaches the process of preparing and the use of the tablets prepared for treating the gastric acid secretion that reads on the instant process and method claims. Lovgren does not teach a combination of proton pump inhibitor and a non-steroidal anti-inflammatory agent.

EP teaches a pharmaceutical composition for the treating the symptoms of overindulgence comprising an analgesic effective amount of acetaminophen or a NSAID and a gastric acid inhibiting effective amount of a proton pump inhibitor. EP teaches that overindulgence is usually caused by excessive or inappropriate food intake and/or alcoholic beverages and results in acid indigestion or sour stomach. EP further teaches no single agent can effectively provide treatment of multiple symptoms of overindulgence. EP also teaches that NSAIDs, used for treating pain and inflammation, themselves cause stomach upset and therefore a combination of drugs is effective in treating the acid indigestion. EP also teaches various doses of NSAID and proton pump inhibitors, depending the specific drug used (col. 6).

While Lovgren suggests coating the core with several protective layers, neither EP nor Lovgren teach the separation of the first component from the second component containing NSAID with an enteric coating covering the first component.

Depui teaches an oral dosage form comprising a PPI and an antibacterial compound, in which the PPI is in multiple units layered with an enteric coating (col. 2, lines 55-68). Fig. 2 of Depui shows a cross-section of a tablet with two separate layers, one layer comprises enteric coating layered pellets of an acid susceptible PPI (1) in

admixture with excipients and the other layer comprises the antibacterial compound(s). Thus, the dosage form of '344 possesses the same structure as that of instant claim 1, except that the dosage of '344 lacks NSAID. The tablet of figure 2 is further covered by an over-coating layer. Depui teaches that the multiple dosage form permits stability over a long time. Depui also teaches several layered dosage form with one layer having PPI, and another layer with an antibacterial (as in Fig. 2) and also a separating layer separating the enteric layer from PPI (col. 3, L 22-30, col. 8) and reads on claims 4 and 14.

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use a non-steroidal anti-inflammatory compound of EP together with a proton pump inhibitor, such as omeprazole of Lovgren or of Depui because EP teaches that a combination of proton pump inhibitor and NSAID is better in treating acid indigestion than either alone and that NSAIDs themselves cause acid indigestion. Thus, a skilled artisan would have expected to provide effective treatment of gastric acid secretion with a combination of proton pump inhibitor and a NSAID. Further, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the dosage form containing a PPI (Lovgren or Depui) and NSAID (EP) in the form of a PPI core covered by an enteric coating and separated by a separating layer from a second component containing NSAID because Depui suggests that a dosage form with multiple layers and multiple units of different drugs can be used for releasing different drugs at the same or different time intervals from the same composition and also for the long term stability of the composition (col. 1, field of the

invention, col.2, lines 5-16, lines 20-27). The expected result would be to provide effective treatment of gastric acid secretion with a combination of proton pump inhibitor and a NSAID, and also provide storage stability ad differential release of the drugs as desired. Further, optimizing the amounts of each of the compounds, depending on the specific drug being employed so as to achieve the desired release would have been within the scope of a skilled artisan.

2. Claims 1, 4-14, 23-28, 32-34 and 37-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,365,184 respectively.

Examiner notes that a terminal disclaimer has been filed previously and accordingly, the double patenting rejection has been withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

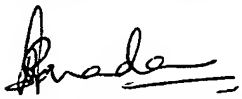
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

May 15, 2006